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No. 03-1014

Supreme Court, U.S.
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In The

Supreme Court of the United States

ELI LILLY & CO.,

Petitioner,

v.

BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

RESPONDENT'S BRIEF IN OPPOSITION

Of Counsel:
JAMES L. QUARLES III
HENRY N. WIXON
HALE AND DORR LLP
The Willard Office Building
1455 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 942-8400

WILLIAM F. LEE
Counsel of Record
LISA J. PIROZZOLO
HALE AND DORR LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

Counsel for Respondent

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COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTION PRESENTED

The United States patent laws provide that "[w]henever an application is made for a patent which, *in the opinion of the Director* [of the United States Patent and Trademark Office], would interfere with any pending application, or with any unexpired patent, an interference *may* be declared[.]" 35 U.S.C. § 135(a) (emphases added). The question presented is:

Whether the Patent and Trademark Office exceeded its discretion under 35 U.S.C. § 135(a) by refusing to conduct an interference between a "species" claim to a specific cDNA sequence coding for a particular human protein and a "genus" claim to the class of cDNA sequences coding for that protein on the grounds that under the agency's interference rules the species and genus claims were not directed to "the same patentable invention"?

PARTIES TO THE PROCEEDING BELOW

Eli Lilly & Company and the Board of Regents of the University of Washington were the parties to the proceedings below. ZymoGenetics, Inc., which licensed the patent at issue from the University of Washington, is a real party in interest. The Novo Group (including Novo Nordisk A/S and Novo A/S) owns 10 percent or more of the stock of ZymoGenetics.

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CONSTITUTIONAL AND STATUTORY PROVISIONS

35 U.S.C. § 146 (in relevant part)

> Civil action in case of interference
>
> Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days, as the Director appoints or as provided in section 141 of this title, unless he has appealed to the United States Court of Appeals for the Federal Circuit, and such appeal is pending or has been decided. In such suits the record in the Patent and Trademark Office shall be admitted on motion of either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.

35 U.S.C. § 282 (in relevant part)

> Presumption of validity; defenses
>
> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.

35 U.S.C. § 291

Interfering Patents

The owner of an interfering patent may have relief against the owner of another by civil action, and the court may adjudge the question of the validity of any of the interfering patents, in whole or in part. The provisions of the second paragraph of section 146 of this title shall apply to actions brought under this section.

37 C.F.R. § 1.601(j)

Scope of Rules, Definitions

(j) An *interference-in-fact* exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

37 C.F.R. § 1.601(m)

Scope of Rules, Definitions

(m) A *senior party* is the party with the earliest effective filing date as to all counts or, if there is no party with the earliest effective filing date as to all counts, the party with the earliest filing date. A *junior party* is any other party.

37 C.F.R. § 1.601(n)

Scope of Rules, Definitions

(n) Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a *separate patentable*

invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and nonobvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

37 C.F.R. § 1.602 (in relevant part)

Interest in applications and patents involved in an interference

(a) Unless good cause is shown, an interference shall not be declared or continued between (1) applications owned by a single party or (2) applications and an unexpired patent owned by a single party.

37 C.F.R. § 1.608 (in relevant part)

Interference between an application and a patent; *prima facie* showing by applicant

(a) When the effective filing date of an application is three months or less after the effective filing date of a patent, before an interference will be declared, either the applicant or the applicant's attorney or agent of record shall file a statement alleging that there is a basis upon which the applicant is entitled to a judgment relative to the patentee.

(b) When the effective filing date of an application is more than three months after the effective filing date of a patent, the applicant, before an interference will be declared, shall file evidence which may consist of patents or printed publications, other documents, and one or more affidavits which demonstrate that applicant is *prima facie* entitled to a judgment relative to the patentee and an explanation stating with particularity the

> basis upon which the applicant is *prima facie* entitled to the judgment. . . . If an examiner finds an application to be in condition for declaration of an interference, the examiner will consider the evidence and explanation only to the extent of determining whether a basis upon which the application would be entitled to a judgment relative to the patentee is alleged and, if a basis is alleged, an interference may be declared.

STATEMENT OF THE CASE

The United States Patent and Trademark Office ("PTO") has discretion to conduct patent interference proceedings pursuant to 35 U.S.C. § 135(a). In accordance with that statutory authority, the PTO has promulgated rules to govern the conduct of interference proceedings, *see* 37 C.F.R. §§ 1.601-1.690, including a rule providing that interferences will only be conducted between patent claims directed to the "same patentable invention." 37 C.F.R. § 1.601(j).

In this case the PTO did nothing more than apply its own interference rules to conclude that certain patent claims of Petitioner Eli Lilly & Company ("Lilly") and Respondent Board of Regents of the University of Washington ("UW") were not directed to the same patentable invention, and therefore not properly the subject of an interference proceeding.

A. The Patent Statute Affords the Patent and Trademark Office Discretion to Conduct or Decline to Conduct Interferences

The United States patent laws permit the PTO to determine whether two patent applications (or a patent

application and an issued patent) are drawn to the "same patentable invention" and, if so, to conduct an interference proceeding to decide priority of invention, *i.e.*, who was first to invent the claimed subject matter and is therefore entitled to the patent. *See Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1100-01 (Fed. Cir. 1994), *cert. denied*, 513 U.S. 1016 (1994). The statute governing interference proceedings before the PTO makes clear that declaration of an interference is discretionary, stating in pertinent part that "[w]henever an application is made for a patent which, *in the opinion of the Director*, would interfere with . . . any unexpired patent, an interference *may* be declared[.]" 35 U.S.C. § 135(a) (emphases added).

Pursuant to 35 U.S.C. § 135(a), the PTO has enacted various regulations governing the declaration and conduct of interference proceedings. *See, e.g.*, 37 C.F.R. §§ 1.601-1.690. One of the rules provides that the PTO will only conduct an interference when patent claims are directed to the "same patentable invention." 37 C.F.R. § 1.601(j). The PTO rules define "same" and "separate" patentable inventions as follows:

> Invention "A" is the *same patentable invention* as an invention "B" when invention "A" is the same as (35 U.S.C. [§] 102) or is obvious (35 U.S.C. [§] 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A." Invention "A" is a *separate patentable invention* with respect to invention "B" when invention "A" is new (35 U.S.C. [§] 102) and non-obvious (35 U.S.C. [§] 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A."

37 C.F.R. § 1.601(n).

When Rule 601(n) was adopted in 1984 as part of a major overhaul of the PTO's regulations, the agency explicitly addressed the issue of whether genus and species claims define "same" or "separate" patentable inventions.[1] The PTO concluded that "if a species is patentable over a genus, the species is a 'separate patentable invention' from the genus."[2] 49 Fed. Reg. 48,416, 48,433 (Dec. 12, 1984).

Approximately fifteen years later, in *Winter v. Fujita*, 53 U.S.P.Q.2d 1234, 1243 (Bd. Pat. App. & Int. 1999), the Board of Patent Appeals and Interferences further clarified the PTO regulations governing "same" and "separate" patentable inventions, clearly stating that it would apply a so-called "two-way" patentability analysis in deciding whether to declare an interference between patent claims. In a case involving priority between inventions A and B, the "two-way" test requires that Invention A anticipates or renders obvious Invention B *and* Invention B anticipates or renders obvious Invention A in order for an interference to be declared. *See id.* The explicit adoption of the two-way test effectively maintained the agency's prior position that no interference would be declared between genus and

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[1] "Genus" claims are directed to a class, such as UW's claim to cDNA sequences coding for a particular human protein. In contrast, "species" claims are directed to a specific subpart of the genus, such as Lilly's claims to a specific cDNA sequence coding for that protein.

[2] *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001).

species claims, so long as the species was patentable over the genus.[3]

In adopting the "two-way" test, the PTO rejected a more inclusive "one-way" test, which would result in an interference if Invention A anticipated or rendered obvious Invention B *or* Invention B anticipated or rendered obvious Invention A. The one-way test would, therefore, always result in interferences between genus and species claims, even if the species (as is often the case) was ultimately found to be later invented and patentable over the genus. The PTO's adoption of the more restrictive two-way test effectively ensured that interferences would only be conducted in circumstances where there was no possibility of two patentable inventions.

After the *Winter* decision, the PTO requested public comment on whether to abandon the two-way patentability test and adopt the more inclusive one-way test. *See* 65 Fed. Reg. 79,809, 79,809-10 (Dec. 20, 2000). In soliciting the comments, the PTO articulated serious concerns with

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[3] Lilly's assertion that the two-way test is "not long-standing" (Pet. at 22) is incorrect. Prior to and after the adoption of Rule 601(n), the PTO took the position that genus and species could be patentably distinct. *See, e.g., Hester v. Allgeier,* 687 F.2d 464, 465-67 (C.C.P.A. 1982) (affirming the Board's holding that a count to a genus and a count to a species within the genus were patentably distinct); *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988) ("There is no inconsistency in awarding a generic count to one inventor, while awarding a patentably distinct species count to another, however."); *Chiong v. Roland,* 17 U.S.P.Q.2d 1541, 1544 (Bd. Pat. App. & Int. 1990) (citing the 1984 Notice of Final Rules as pointing out that "the standard of patentability will not be applied 'on a mutual basis'" and stating "[i]f a species claim is patentable over a generic claim, the species claim is a separate patentable invention from the generic claim.")

adopting the expansive one-way test for which petitioner now advocates. *See id.* Significantly, the PTO noted the strain on resources and other problems that adoption of a one-way test would cause:

> Any decision to expand the nature of interference proceedings will have a resource consequence for USPTO and for applicants and patentees involved in interferences. Approximately one-quarter of the resources of the Board of Patent Appeals and Interferences are used to resolve interferences, notwithstanding the fact that there are many more appeals than interferences. USPTO has received many reports that interferences involve considerable costs for applicants and patentees. Additionally, there is no desire on the part of USPTO, and no authority under the law, to turn interference proceedings under 35 U.S.C. [§] 135(a) into pre-grant oppositions or post-grant cancellations. Accordingly, USPTO is reluctant, at this time, to expand the circumstances under which an interference might be declared or maintained absent a compelling reason.

Id. at 79,810. Ultimately, after reviewing the comments, the PTO reiterated its intention to retain the two-way patentability test. *See* Board of Patent Appeals and Interferences, Answers to Frequently Asked Questions (June 7, 2001), at pp. 5-6, *at* www.uspto.gov/web/offices/dcom/bpai/bpaifaq.htm.

More recently, the PTO has published notice of its intention to amend its rules to make even more clear that

the two-way test applies.[4] *See* 68 Fed. Reg. 66,648, 66,664-65 (Nov. 26, 2003). In its notice of the proposed rule, the PTO has stated that "[t]he Director uses a two-way unpatentability test to determine whether claimed inventions interfere because, while a one-way test is only sufficient for rejecting a claim under 35 U.S.C. [§] 102(g), a two-way test is necessary to ensure that the claims of both parties are directed to the same invention." *Id.*

B. The Patent Office Simply Applied Its Rules in this Case

In November 1998, Lilly filed a reissue patent application for the purpose of provoking an interference proceeding with three issued patents assigned to UW, including United States Patent No. 5,302,529 (the "Foster patent"). Lilly's reissue application included species claims to a specific cDNA sequence coding for human protein C, which plays an important role in the regulation of blood coagulation. UW's Foster patent included not only species claims to a specific cDNA sequence coding for human protein C, but also a broader genus claim to the class of nucleotide sequences coding for human protein C.

In order to provoke an interference between the Lilly reissue application and UW's Foster patent, Lilly repeatedly (and incorrectly) told the PTO that its reissue application and the Foster patent included claims to identical

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[4] Proposed rule 37 C.F.R. § 41.203(a) would clarify that an "interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." 68 Fed. Reg. 66,648, 66,689 (Nov. 26, 2003).

cDNA sequences, and thereby included claims to the "same patentable invention." Based on Lilly's erroneous assertions, the PTO declared an interference proceeding between the respective species claims of Lilly's reissue application and the Foster patent. Only after UW sought to have the PTO declare that no interference existed did Lilly admit that its assertions had been wrong, and that the cDNA sequences of the claims involved in the interference were different.

Lilly then urged the PTO not to terminate the interference on the grounds that Lilly's species claims and UW's genus claim[5] to the class of cDNA sequences coding for human protein C were directed to the "same patentable invention." The PTO, applying its regulations, held that UW's genus claim (construed broadly) and Lilly's species claims were "separate patentable inventions" because Lilly's species claims were patentable over UW's genus claim.[6] As a consequence, the PTO refused to conduct an interference proceeding to determine priority of inventorship between the species claims in Lilly's reissue application and the genus claim in the Foster patent.

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[5] Based on Lilly's factual misrepresentations, the PTO had not included UW's genus claim in declaring the interference. During the proceedings before the PTO, Lilly declined actually to admit that UW's genus claim did, in fact, cover Lilly's claimed species. Instead, Lilly proposed alternative claim constructions for the claim (a broad genus or a narrow species) and asked the PTO to make a choice. The PTO declined to do so, but did thoroughly analyze both constructions in concluding that there was no interference in fact.

[6] Given that the PTO explicitly considered the issue of whether to continue the interference between UW's genus claim and Lilly's species claims, the assertion in Lilly's petition that the "Board did not choose to consider UW's genus claim" (Pet. at 5) is incorrect.

C. The Federal Circuit Properly Recognized the PTO's Discretion to Use a Two-Way Test Generally, and in this Particular Case

Lilly appealed the PTO's decision to the Federal Circuit, which affirmed the agency determination. That court held that the declaration of an interference is discretionary, according to the plain meaning of 35 U.S.C. § 135. In addition, based on the submission of an amicus brief by the Director of the PTO, the Federal Circuit found that the PTO interprets its own Rule 601(n), defining "same" and "separate" patentable inventions, as requiring a "two-way" test. Finally, the Federal Circuit held that the PTO's application of a "two-way" test under its own regulations was a permissible exercise of the agency's discretion under Section 135(a).[7]

In deciding that the PTO had not exceeded its discretion, the Federal Circuit explicitly noted that the PTO's adoption of a two-way test was not plainly erroneous or inconsistent with the PTO's regulations. The Federal Circuit also observed that, as a policy matter, the two-way test avoids the proliferation of unnecessary, wasteful interference proceedings in situations where the claimed inventions do not define the same patentable invention, but merely overlap in scope. In the specific context of

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[7] Lilly incorrectly asserts that the Federal Circuit construed Section 135(a) "to mean that the PTO has complete, unrestrained discretion to interpret its rules as it chooses." (Pet. at 7.) In fact, the court below simply stated that the PTO's interpretation of its own regulations "is controlling unless 'plainly erroneous or inconsistent with the regulation.'" (Pet. App. 11, *citing Auer v. Robbins*, 519 U.S. 452, 461 (1997)). The Federal Circuit further concluded that the PTO's use of a two-way test "easily met" the deferential standard. (Pet. App. 12.)

genus and species claims, the two-way test ensures that the PTO does not conduct a lengthy and costly interference proceeding only to conclude that a later invented species is separately patentable over an earlier invented genus.

Lilly requested a rehearing by the Federal Circuit sitting *en banc*. In connection with the petition for rehearing, only four amicus briefs were submitted. Of the three in favor of the one-way test, two were filed by or on behalf of a law firm that, by its own account, handles more interferences than any other law firm in the country. The Director of the PTO submitted the only other amicus brief, stating that 35 U.S.C. § 135(a) "makes abundantly clear that the Director has discretion to determine the type of test used for interference proceedings" and that the "two-way test is consistent with the patent laws." (PTO Amicus Brief filed September 9, 2003 at 1-2.)

The Federal Circuit denied the request for rehearing.

REASONS FOR DENYING THE WRIT

A. The Decision Below is Consistent with the Plain Language of the Statute Governing Interferences, and with the Precedent of this Court and the Federal Circuit

1. The Plain Language of the Statute and Case Law Dictate Deference to the Discretion of the PTO

The Federal Circuit properly recognized that declaration of an interference by the PTO is discretionary pursuant to 35 U.S.C. § 135(a), which states that an interference "*may*" be declared if "*in the opinion of the Director*" it

appears that two parties are claiming the same invention. (Pet. App. 8.) That court also correctly held that the PTO's use of a two-way test under 37 C.F.R. 1.601(n) to determine whether claims are directed to the "same patentable invention" constitutes "the clear application of discretion that is inherent in the authority granted pursuant to 35 U.S.C. § 135(a)[.]" (Pet. App. 11.)

Hardly a departure from controlling case law, the Federal Circuit's decision is consistent with longstanding precedent from this Court. In *Ewing v. United States ex Rel. The Fowler Car Co.*, 244 U.S. 1, 10 (1917), the Court held that the language "in the opinion of the Commissioner" in the predecessor statute to Section 135(a) gave the Commissioner of Patents discretion to decline to proceed with an interference proceeding.[8] The decision below is also consistent with Federal Circuit precedent holding that "[t]he plain meaning of [35 U.S.C. § 135(a)] is clear from the use of the permissive term 'may' that the [Director] has discretion whether to declare an interference." *Barton v. Adang*, 162 F.3d 1140, 1144 (Fed. Cir. 1998). *See also Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050 (Fed. Cir. 1994) (the Federal Circuit reviews a Board decision pursuant to the permissive rules governing a patent interference proceeding for abuse of discretion.)

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[8] Lilly attempts to diminish the importance of the precedent set by *Ewing* on the grounds that it involved different facts. (Pet. at 19.) *Ewing*, however, clearly recognized the broad discretion of the PTO to declare interferences. Furthermore, the *Ewing* Court gave no indication that its statements regarding the PTO's discretion were confined to the particular facts of that case.

2. Section 135(a) Does Not Conflict with Other Provisions of the Patent Statute or with Prior Case Law

Notwithstanding the clear congressional intent under 35 U.S.C. § 135(a) to grant the PTO discretion to conduct interferences, Lilly asserts that Rule 601(n), as interpreted by the PTO, is contrary to the "Patent Statute" and a body of case law generally stating that "only one patent should issue for inventions which are either identical to or not patentably distinct from each other." (Pet. at 10.) Lilly's claim of a "conflict" is erroneous for at least three reasons.

First, nothing in any provision of Title 35 cited by Lilly explicitly or implicitly limits the permissive language of Section 135(a) – the only provision in the Patent Statute that addresses interferences. *See Morton v. Mancari*, 417 U.S. 535, 550-51 (1974) (enforcing "specific provision, applying to a very specific situation" and noting that "courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective"). Lilly provides no basis upon which the Court would be permitted to ignore the plain language of 135(a) in favor of other provisions in the Patent Statute that do not even mention interferences.[9]

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[9] Lilly's citations (Pet. at 12) to cases in which this Court has found that agencies exceeded their statutory authority are inapplicable here. For example, *MCI Telecomms. Corp. v. American Tel. and Tel. Co.*, 512 U.S. 218, 225 (1994), simply involved the correct interpretation of the word "modify" in a statute. Similarly, *United States v. Larionoff*, 431

(Continued on following page)

Second, the cases and statutes Lilly cites to support its claim of a "conflict" (Pet. at 10) do not demonstrate a conflict at all. For example, in *Aelony v. Arni*, the Federal Circuit's predecessor held that the "test of interference in fact is not whether two sets of claims overlap, but whether they are patentably distinct from *each other*." 547 F.2d 566, 570 (C.C.P.A. 1977) (emphasis added). *Aelony's* holding hardly conflicts with the two-way test, and was actually cited by the PTO to support its dismissal of the interference at issue here.

Other cases Lilly cites say nothing about the correct standard for the declaration of interferences in the PTO, and simply stand for the general proposition that only one patent should issue for one invention. *See, e.g., Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001), *cert. denied*, 534 U.S. 1172 (2002). Lilly's assertion that the PTO's two-way test conflicts with these cases rests upon the false premise that its species claim and UW's genus claim are necessarily directed to the "same patentable invention." That premise is not true here and it is not true in many cases involving genus and species claims. As the PTO and the Federal Circuit have both stated, species and genus claims are not always directed to the same patentable invention. A later species claim can be patentably distinct from an earlier genus

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U.S. 864, 873 (1977), merely expressed the uncontroversial proposition that agency regulations must be consistent with the statutory authority pursuant to which they are promulgated. In this case, the grant of discretion to the PTO in 35 U.S.C. § 135 is clear and unambiguous, and requires no statutory construction.

claim.[10] *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001). Thus, the use of a two-way test simply ensures that interferences will not be conducted in cases where one possible outcome is two patentable inventions – one to a genus and one to a species.

Finally, the mere possibility that UW's genus claim and Lilly's species claim are not separately patentable, does not require that the PTO make a priority determination. Pursuant to Title 35, the PTO and the federal courts share responsibility for addressing patentability issues, including priority of invention under 35 U.S.C. § 102(g). In addition to the PTO interference proceedings provided in Section 135, patentees have the option to pursue interference proceedings in the federal courts under 35 U.S.C. §§ 291 and 146. Furthermore, in the event of an actual case or controversy involving the Lilly or UW patents (such as a patent infringement lawsuit), the federal courts will have jurisdiction to address the priority issue.

Thus, while Lilly may believe, as a policy matter, that priority issues are best resolved in administrative proceedings before the PTO rather than in the courts, nothing in Title 35 dictates such a conclusion. Indeed, this Court long ago rejected such an argument, noting that the judicial remedy provided by the predecessor to 35 U.S.C. § 291 adequately addressed any potential loss of rights caused

[10] For example, in this case an interference could result in the conclusion that UW's genus claim was first, and Lilly's species claim was second but nevertheless patentable over UW's genus claim. The two claims could thus coexist as separate patentable inventions, and the interference would have been unnecessary.

by the PTO's failure to proceed with an interference proceeding under the predecessor to 35 U.S.C. § 135. *See Ewing*, 244 U.S. at 10 (describing party's right to seek a judicial remedy under the predecessor statute to 35 U.S.C. § 291 and noting that "there is no defeat of ultimate rights; there may be *postponement* of their assertion remitted to a suit in equity[.]") (emphasis added).

In sum, the "statutory scheme" articulated in 35 U.S.C. § 135(a) clearly grants the PTO discretion to declare interferences, and the PTO's use of a "two-way" test falls well within the bounds of that discretion.

B. Judicial Interference with the PTO's Discretion Under 35 U.S.C. § 135(a) Would Have Adverse Consequences

Even if one were to accept the assertion (contrary to the plain language of 35 U.S.C. § 135 and the case law) that declaration of interference proceedings is not discretionary with the PTO, ordering the PTO to use a one-way test in determining whether to conduct interferences would cause more harm than good, and would cast uncertainty upon other interference rules involving agency discretion.

1. The "One-Way Test" Would Do More Harm Than Good

As has been noted by both the PTO and the Federal Circuit in its decision below, the one-way test advocated by Lilly would require the PTO to conduct interference proceedings in many priority contests involving patents and patent applications with broad and narrow claims. For example, the one-way test would include all instances in

which two pending applications (or a pending application and an issued patent) included genus-species claims, combination-subcombination claims, or improvement-subimprovement claims. In so doing, the one-way test would drag into interference practice many disputes in which an interference would ultimately be found not to exist (*e.g.*, in all cases involving later-filed, but patentably distinct species claims). The over-inclusive one-way test would thus result in unnecessary costs to the parties involved in interference proceedings as well as to the PTO. In addition, use of the one-way test would permit parties to provoke interference proceedings between pending applications or between issued patents (as was the case with Lilly here) by filing reissue applications and drawing issued patents into further protracted proceedings before the PTO.

When the PTO solicited comments on the one-way test, these concerns were raised:

> Converting to a one-way test would mean that improvement patents could always be in interference with the broader patents on which they improve, patents containing combination claims could always be in interference with patents containing broader subcombinations, patents containing species claims could always be in interference with patents containing broader genus claims, etc.

Comment of William P. Berridge on 0651-AB29: Standard for Declaring a Patent Interference (February 26, 2001), *at* http://www.uspto.gov/web/offices/dcom/bpai/rule/wberridge.htm. Other commentators have remarked upon the frustration of patentees (such as UW) who find themselves

dragged into protracted interference proceedings in the PTO:

> Once applicants survive [the application] process and successfully win the prize of being issued a patent, it is unsettling for the patentee to be put to the test yet again, especially in an interference context with a potentially aggressive and relentless opponent. Subjecting a patentee to unnecessary further scrutiny is also contrary to the primary function of the PTO.

Comment of Edward Kenehan on 0651-AB29: Standard for Declaring a Patent Interference *at* http://www.uspto.gov/web/offices/dcom/bpai/rule/ekenehan.htm. Indeed, in affirming its decision to follow the two-way test, the PTO noted the strain on resources and other changes that use of a one-way test would cause. *See* 65 Fed. Reg. 79,809, 79,810 (Dec. 20, 2000).

The Federal Circuit also noted the difficulty posed by species and genus claims.[11] The two-way test may be under-inclusive, insofar as it may not result in an interference between a presumptively prior species claim and a later genus claim. On the other hand, the one-way test advocated by Lilly would be over-inclusive, and result in declaration of interference proceedings between presumptively prior genus claims and later species claims. The

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[11] Lilly's assertion that the Federal Circuit acknowledged the "evils" of the two-way test is overstated, particularly with regard to its repeated use of the word "evil" to describe the administrative rule at issue. (Pet. at 8.) In fact, the Federal Circuit simply acknowledged the competing policy considerations motivating the PTO's adoption of the two-way test. (Pet. App. 14.)

Federal Circuit properly concluded that the PTO's choice of the under-inclusive two-way test rather than an over-inclusive one-way test constituted a permissible exercise of the agency's discretion under 35 U.S.C. § 135(a).

Lilly's attacks on the PTO for even considering efficiency and the proper allocation of resources in adopting the two-way test are unwarranted. For example, Lilly states "it defies logic" that the PTO has declined to conduct certain interferences on the grounds that it "wants to save money." (Pet. at 21.) Notwithstanding Lilly's strident tone, government agencies such as the PTO are often required to make difficult decisions concerning resource allocation. Indeed, Lilly's argument, taken to the extreme, would require the PTO to take every possible step, with no regard to "saving money," to ensure against the issuance of invalid patents. For example, in addition to requiring the PTO to conduct interference proceedings in all cases involving genus and species claims, such steps could require that patent examiners take on far fewer cases, conduct their own factual investigations for prior sales of the claimed invention, or conduct their own experiments (in a PTO laboratory built and equipped for that purpose) to independently verify the accuracy or reliability of a patent applicants' assertions. These are all costly actions that could diminish the chances of an invalid patent issuing, but would also jeopardize the fair and efficient operation of the agency. In sum, Lilly's contention that decisions be made without regard to resources is neither realistic nor supported by the statutory scheme. The PTO, which has a broad perspective and experience, is better able than the courts to allocate its own resources, and has properly done so here.

2. Abrogating the PTO's Discretion to Conduct Interferences Could Impact PTO Rules Other Than 601(n)

Rule 601(n) is not the only PTO rule that limits the type of cases in which the PTO will conduct interference proceedings.[12] Other rules exclude from interference practice situations that could possibly result in the PTO's issuance of two patents, one of which is presumptively invalid. (Pet. at 11.) For example, pursuant to 37 C.F.R. § 1.602, the PTO will not declare or continue an interference between applications (or between an application and an unexpired patent) owned by a single party, unless good cause is shown. Thus, in cases where one assignee obtains a patent on a genus claim and later seeks to obtain a patent on the species, no interference is declared absent good cause. If the PTO was required to conduct interferences in such cases, the number of interferences would greatly increase.[13]

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[12] Indeed, PTO administrative rules designed to streamline interference proceedings have been cited repeatedly and incorrectly by Lilly to attack UW's patent as "presumptively" invalid. *See, e.g.,* Pet. at 11. Under the interference rules, for ease of administration, Lilly is deemed the "Senior Party" solely upon the basis of the application date to which it claims priority. *See* 37 C.F.R. § 1.601(m). UW's issued U.S. patent is presumptively valid. *See* 35 U.S.C. § 282. Lilly's reissue application, by contrast, is entitled to no presumption of validity.

[13] Indeed, certain of the cases Lilly cites to support its assertion that the two-way test "conflicts" with existing Federal Circuit precedent involve situations in which a common assignee has both genus and species claims. *See, e.g.,* Pet. at 13 (*citing Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) and *Geneva Pharm., Inc. v. GlaxoSmithKline P.L.C.*, 349 F.3d 1373 (Fed. Cir. 2003). These cases do not "conflict" with PTO interference rules, insofar as the cases say nothing about whether priority determinations should be made in interference

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Similarly, pursuant to 37 C.F.R. § 1.608(b), an interference will not be declared if the effective filing date of an application is more than three months after the effective filing date of the allegedly interfering patent, absent evidence demonstrating that the applicant is *prima facie* entitled to a judgment relative to the patentee. If such evidence is presented, an interference "may" be declared. 37 C.F.R. § 1.608(b). Even if the effective filing date of the application is less than three months after the effective filing date of the patent, the applicant or the applicant's attorney still needs to file a statement alleging that there is a basis upon which the applicant is entitled to judgment relative to the patentee. *See* 37 C.F.R. § 1.608(a). Thus, the PTO regulations serve to limit interferences to situations in which there is a *bona fide* priority contest with some likely impact.

C. The Unique Circumstances of Lilly's Case Do Not Implicate Matters of Widespread Public Importance to Intellectual Property Owners

Lilly's precise complaint concerns a particularly unique situation in which the PTO declined to conduct an interference between a presumptive senior party (Lilly) with a species claim and a presumptive junior party (UW) with a genus claim. Any assertion that this precise factual circumstance is commonplace would be startling, insofar as it has taken nearly twenty years since the PTO rules

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proceedings before the PTO (rather than by federal courts). If anything, the cases cited by Lilly demonstrate that under the Patent Statute priority matters are capable of being addressed by the courts if and when they arise in the context of an actual patent dispute.

were promulgated in 1984 for this factual scenario even to reach the Federal Circuit. Thus, while this case is important to Lilly because it involves a patent covering Xigris®, one of Lilly's products, the precise facts would not appear to be routine.

Furthermore, even if this particular situation were replicated, the alleged harms of the PTO's two-way test referenced by Lilly are speculative, at best. Indeed, the only harm articulated is the possibility of "the public" or Lilly being subjected to a patent infringement suit by UW. Notably, no member of the "public" has raised such an issue. More importantly, however, if such a dispute were to arise, the federal courts would have jurisdiction to determine whether UW's patent was enforceable. Requiring Lilly to wait to adjudicate the validity of UW's patent until such time as an actual case or controversy exists is entirely consistent with the Patent Statute.

In order to bolster its contention that the patent system "as a whole" is harmed by the PTO's use of the two-way test, Lilly cites extensively to a recent report of the Federal Trade Commission ("FTC") entitled *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, 2003 WL 22507757 (F.T.C. October, 2003), in which the FTC discussed the harms caused by the issuance of invalid patents. (Pet. at 15-17.) The FTC report, however, says nothing about abandoning the two-way test or altering the conduct of interference proceedings.[14] Furthermore, the FTC report (unlike Lilly) clearly

[14] In the report, the FTC explicitly stated its intention to file amicus briefs in "important patent cases" with "high stakes for the

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acknowledges that certain of its proposed changes to the patent system must be accomplished by legislative amendment. For example, in its report, the FTC has proposed introducing an administrative procedure pursuant to which parties can challenge the validity of a patent in a proceeding before the PTO, without having to wait for federal court litigation, as is currently the case. *See id.* at *7 (Executive Summary, pp. 7-8). However, given that the Patent Statute does not currently give the PTO jurisdiction to conduct such post-grant opposition proceedings[15] (a distinction between the United States patent system and certain systems abroad), the FTC recognized that any post-grant review and opposition must be accomplished through authorizing legislation. Finally (and importantly), the FTC report (unlike Lilly) explicitly acknowledged the serious resource shortages at the PTO, noting the unanimous view that "the PTO does not receive sufficient funding for its responsibilities." *Id.* at *8 (Executive Summary, p. 10). The FTC report does not, therefore, provide any support for the proposition that the Court abrogate the explicit discretion of 35 U.S.C. § 135(a) to impose a one-way test on the PTO.

public." *Id.* at *14 (Executive Summary, p. 17). The FTC did not file an amicus brief in the proceedings below.

[15] As was noted in an amicus brief submitted by the PTO in response to Lilly's appeal to the Federal Circuit, the agency's "authority does *not* extend to provide an alternative avenue for third parties to attempt patent correction or cancellation under § 135." (PTO Amicus Brief filed February 4, 2003 at 22; emphasis in original.)

CONCLUSION

Lilly's petition for a writ of certiorari should be denied. The Federal Circuit properly held that the PTO's use of a "two-way" test generally, as well as in connection with the particular facts of this case, constituted an appropriate exercise of the agency's discretion under 35 U.S.C. § 135(a).

Respectfully submitted,

WILLIAM F. LEE
Counsel of Record
LISA J. PIROZZOLO
HALE AND DORR LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

Of Counsel:
JAMES L. QUARLES, III
HENRY N. WIXON
HALE AND DORR LLP
The Willard Office Building
1455 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 942-8400

Attorneys for Respondent